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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,384	08/20/2002	Maria Laura Gennaro	07763-042001	7084
26211 7590 04/10/2007 FISH & RICHARDSON P.C. P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/10/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/009,384

Applicant(s)

GENNARO ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 January 2007 has been entered.

Claims 17, 18, 19, and 20 have been amended. Claims 21-36 have been canceled.

2. Claims 1-8 and 11-20 are pending and under consideration.

### **Rejections Maintained**

3. The rejection of claims 17-20 under 35 U.S.C. 112, first paragraph, scope of enablement for diagnostic methods utilizing polypeptides, is maintained for the reasons of record.

Applicants argue that because the claimed polypeptides are secreted by *M. tuberculosis*, one of ordinary skill in the art would have expected a substantial number of said polypeptides to be useful in the diagnosis of tuberculosis. The examiner has considered applicants' argument, and agrees that because the polypeptides are secreted by *M. tuberculosis*, said polypeptides may be useful for diagnosis of tuberculosis. However, applicants' argument is not drawn to the contended criticality, i.e., that the polypeptides are able to specifically diagnosis *M. tuberculosis*.

Applicants argue that the cited reference, Amor et al, teach that with an *in vitro* assay, and using a cutoff value of +3 S.D., the results did indicate a difference between TB-positive and TB-negative patients sera. The examiner has considered applicants' argument, but does not find it persuasive because the assay of Amor et al is an *in vitro* assay, and the claimed

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assay is an *in vivo* assay "wherein the presence of an immune response to said polypeptide segment is an indication that said subject has a *Mycobacterium tuberculosis* infection". Thus, in applicants' assay, any detectable immune response is determined to label a subject as "TB-positive", not a qualified response as seen in the *in vitro* assay of Amor et al.

Applicants argue that "functional segments" are defined and enabled by the specification as "a segment of the polypeptide that has *Mycobacterium tuberculosis* specific antigenic and immunogenic properties." As such, one of ordinary skill in the art would readily be able to identify segments of these polypeptides having the requisite function (although not necessarily the same level of function as corresponding full-length MSTP polypeptides). The examiner has considered applicants' argument, but does not find it persuasive. The specification is merely speculative concerning an individual polypeptide being able to diagnosis *M. tuberculosis* as is claimed. The specification contains no working examples of the claimed invention, nor working examples of any *M. tuberculosis* specific antigenic and immunogenic properties by which one of ordinary skill would be able to identify segments which fulfill the requirements of the instant claims.

4. The rejection of claims 1-8 and 11-20 under 35 U.S.C. 112, second paragraph, indefiniteness for specific properties and number/identity of conservatively substitutes residues, is maintained for reasons of record.

Applicants' arguments concerning functionality put forth in this rejection response are the same as above.

The examiner has considered applicants' arguments, but does not find them persuasive for the same reasoning put forth above. The instant specification contains no working

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examples of the claimed invention showing that the claimed polypeptides of *M. tuberculosis* comprise the claimed specific antigenic and immunogenic properties.

### **Conclusion**

5. No claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 30, 2007

RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER